Electro-fluidic Interface for Monitoring Brain Injuries

1. Purpose

This document presents the functional requirements for the packaging unit for continuous monitoring of cerebral spinal fluid (CSF) being developed by Dr. Gordon Thomas and his lab in the BioPhysics Department at NJIT.

2. Reason for Re-Issue

ISSUE		REASON FOR RE-ISSUE
1	MR #PACKCSF001	Improve biocompatibility, Improve integration of device with existing shunt systems

3. Overview

The packaging unit is the complement of the SmartShuntTM product headed by Dr. Thomas in the BioPhysics Department at New Jersey Institute of Technology. The packaging unit provides protection for pressure and flow sensors within the SmartShuntTM from the outside (or internal body) environment. The packaging unit also provides a pathway for the execution of Cerebrospinal Fluid (CSF) flow from the ventricles of the brain to the peritoneal cavity (Figure 1).

This document shall use the following annotations:

· ***REQxxxx*** *denotes a* ***specific requirement*** *that must be met.*

· ***BACKxxxx*** *denotes an* ***information*** *statement that may be useful in interpreting requirements and the numbering should match the requirement number.*

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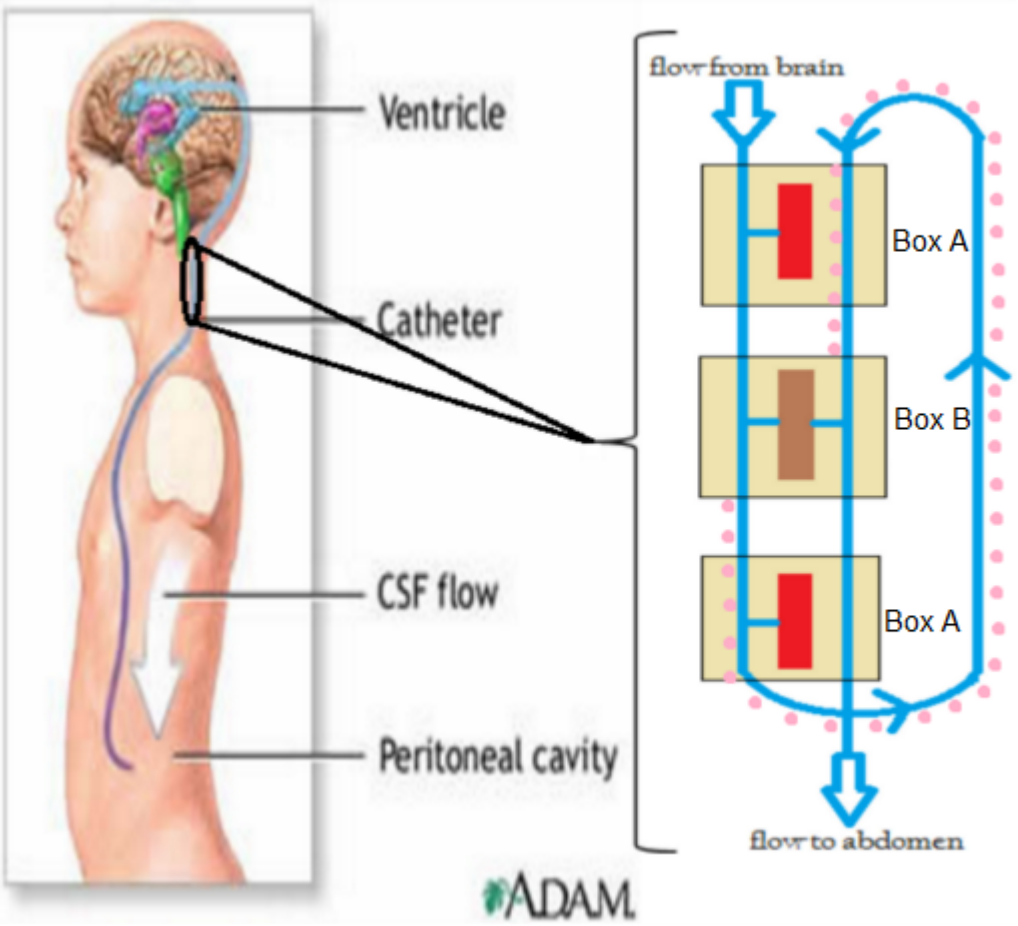


FIGURE 1: *Proposed Flow Path: the CSF flows in from the brain and touches all three sensors (pressure sensors shown in red in Box A and flow sensor shown in brown in Box B) on the first pass through. The flow then loops back and passes through again but this time the flow only touches the flow sensor. The exiting flow goes to the peritoneal cavity. The line of pink dots represents 51 cm of tubing.*

4. Document References

The documents listed below are either cited directly or are useful as supplemental documents used for interpreting the requirements detailed in section 5:

- David Apigo's dissertation paper
- ISO (10993 standard)
- USP (Class VI testing)
- Electro-fluidic Interface for Monitoring Brain Injuries Customer Needs
- Food and Drug Administration specifications for shunt systems

5. Packaging Unit - Functional Requirements

This section provides the functional requirements for the packaging unit .

5.1 Physical Requirements

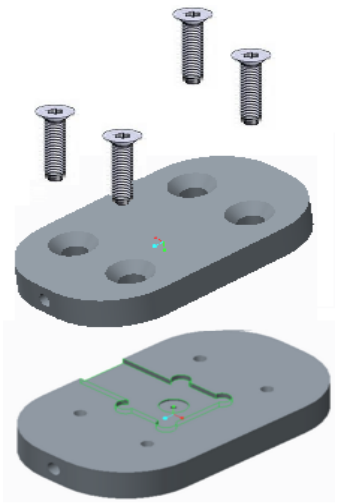
This section provides physical requirements for the complete Packaging Unit used to house capacitive bio-sensors.

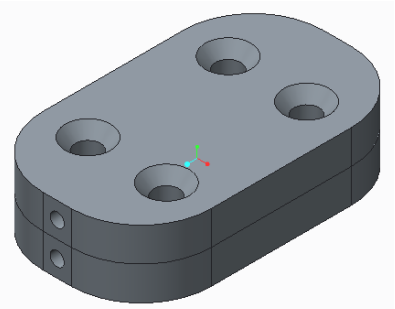
REQ010: Physical Design: The entire unit shall consist of three housing units of printed PMMA (Figure 2).

> **BACK010:** Two of the three units will house pressure sensors (box A in Figure 1) and have one access point to the flowing CSF. The remaining unit will house a flow sensor (box B in Figure 1) and have two access points to the flowing CSF.

REQ020: Singular Sensor Housing: Each housing unit shall be formed by joining an upper and lower printed sheet of PMMA with stainless steel screws, sandwiching the respective sensor to hold it in place via compression (Figure 3).

> **BACK020:** The housing complies with the customer needs for a housing unit with no sharp edges and easily accessible sensors. (Document: Electro-fluidic Interface for M





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Injuries Customer Needs).

Figure 2: *Visual of the three housing units connected with tubing stretched over the stainless steel tubes extruding from each housing unit*

Figure 3: *Assembly of one housing unit.*

REQ021: Dimensions: Each housing unit shall be length *A =1" ± ⅛"* (Figure 4).

REQ022: Dimensions: Each housing unit shall be thickness *¼" ± 1/16"* when assembled, thus, the upper and lower sections of the housing unit have a thickness *B = ⅛" ± 1/32"* (Figure 4).

REQ023: Dimensions: Each housing unit shall be *width C = □" ± 1/16"* (Figure 4).

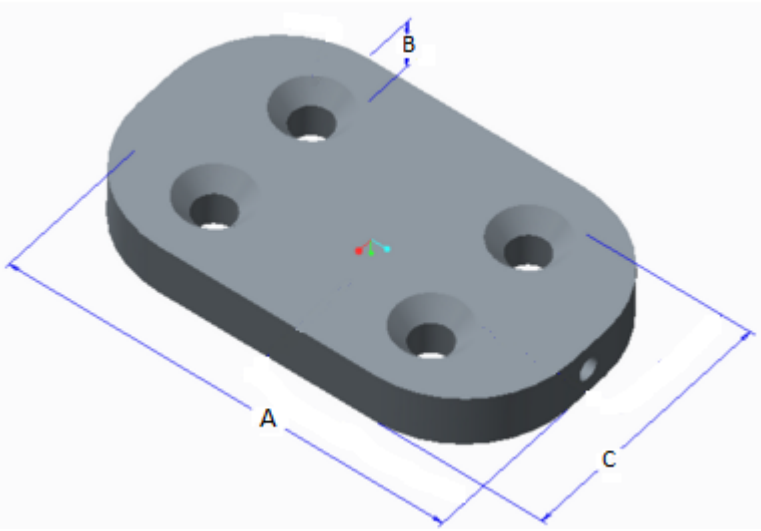

FIGURE 4: *Creo Drawing of the upper half of a housing unit with dimensions.*

REQ024: Edges: Each housing unit shall have rounded edges, with a radius of half the total thickness of the housing unit

REQ030: Screws: Four, Non-magnetic Type 316 Stainless Steel Flat-Head Socket Cap Screw, 2-56 Thread, 3/8" ± 0.001" long shall be used to join the upper and lower sections of each housing unit (Figure 5, top).

REQ031: Dimensions: The upper part of each housing unit shall have four holes of shaft diamater A, Beveled angle B, and head diameter C (Figure 5, bottom) to accommodate the screws.

REQ032: Dimensions: The four holes for the screws shall be ¼" ± 1/32" (X, Figure 6) from the D plane and 0.16 ± 0.005" (Y, Figure 6) from the edge of the straight side.

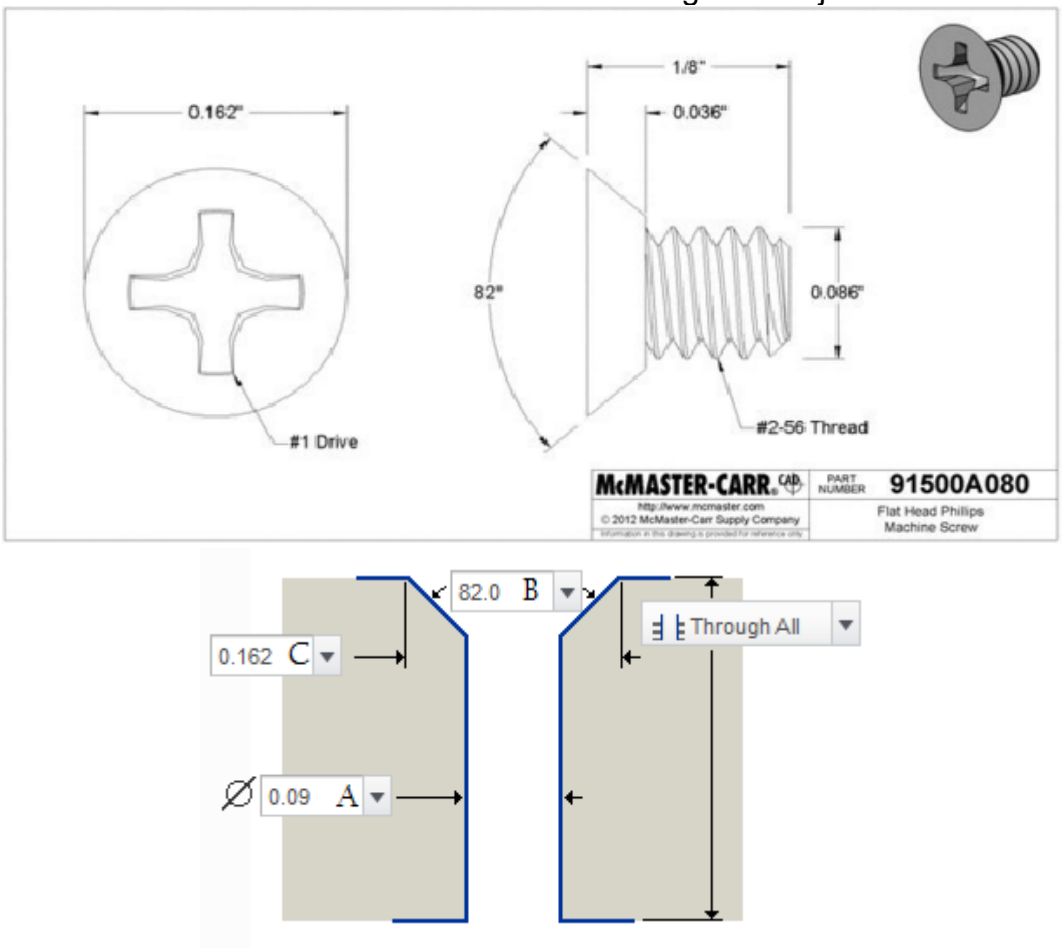

Figure 5: *Dimensions of the stainless steel screws (top) and the dimensions of the hole for the screw in the housing unit (bottom)*

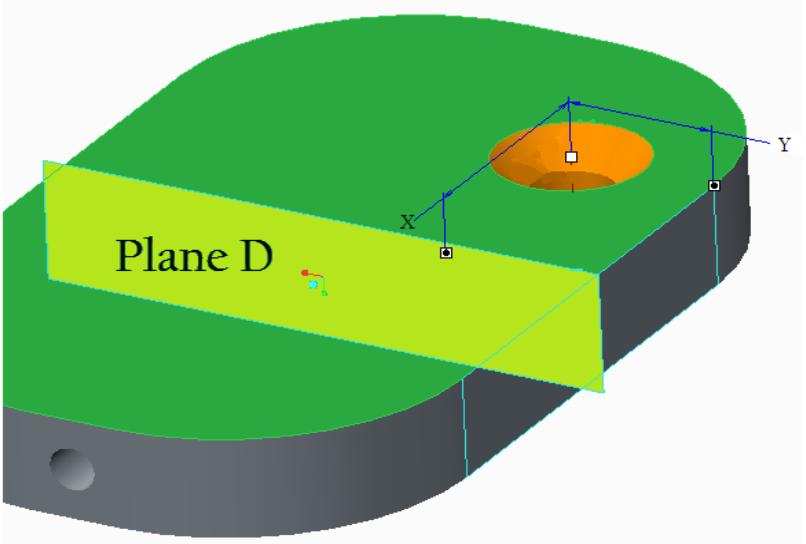

Figure 6: *Hole placement on the upper part of the housing unit to accommodate the screws*

REQ033: Tubing: Tubing with an inner diameter of 0.030" ± 0.001" (X, Figure 7)and Outer Diameter of 0.078" ±0.001" (Y, Figure 7) shall be used for connecting the housing units together.

BACK033A: The inner radius of the tubing is set by the FDA

BACK033B: CSF flows from the ventricles in the brain, through the shunt, to peritoneal cavity via tubing that is stretched over stainless steel tubes extruding from each housing unit. (Figure 2)

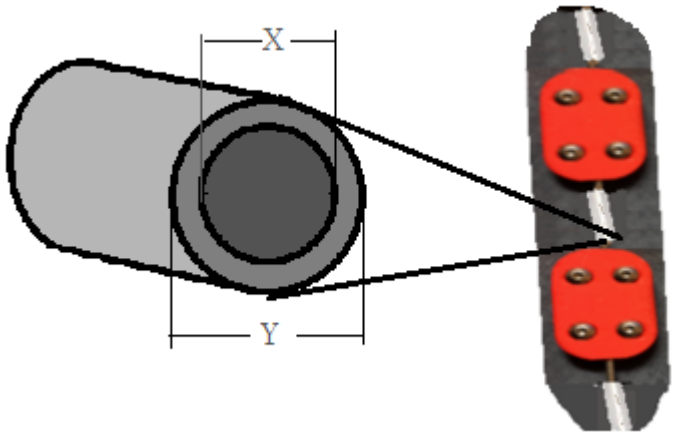

Figure 7: *Tubing dimensions*

REQ034: Tubing: The 51 cm ± 0.5 cm length of tubing (pink dots, Figure 1) that loops back around to re-enter the package shall be confined in a neat and compact manner

REQ040: O-Rings: Fluorcarbon O-Rings with Inner Diameter of A = 0.075" ± 0.001" and cross sectional width of B = 0.012" ± 0.01" shall be used for creating a seal of 15 PSI + 5 PSI between channels and sensors (Figure 8i).

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Figure 8: i) *O-ring dimensions* ii) *o-ring in housing unit* iii) *33% of o-ring exposed above groove*

REQ041: Compression: The compression of the O-Ring, developed by the pressure enacted by the four screws, against the PMMA housing shall create a seal of 15 PS ± 5 PSI around the channel to the sensor (Figure 8ii)

REQ042: 33% ±1% of the O-Ring shall be exposed above the O-ring groove (Figure 8iii).

REQ043: Compression: The four stainless steel screws shall be screwed in until the head of the screw is leveled with the top of the housing unit.

REQ060: Channel Dimensions: The channels within the housing unit shall be *E = 0.03"* ± *0.001"* in diameter (Figure 9).

> **BACK060:** Must match the inner diameter of the stainless steel tubes connecting the housing units.

REQ061: Channel Dimensions: The channel width shall be *F = 0.05"* ± *0.001"* for the first ¼" ± 0.001" to allow for the insertion of stainless steel tubes (Figure 9).

> **BACK061:** The stainless steel tubing will extend into each housing unit *G = 0.25"* ±*0.001"* and be secured with epoxy (refer to REQ150).

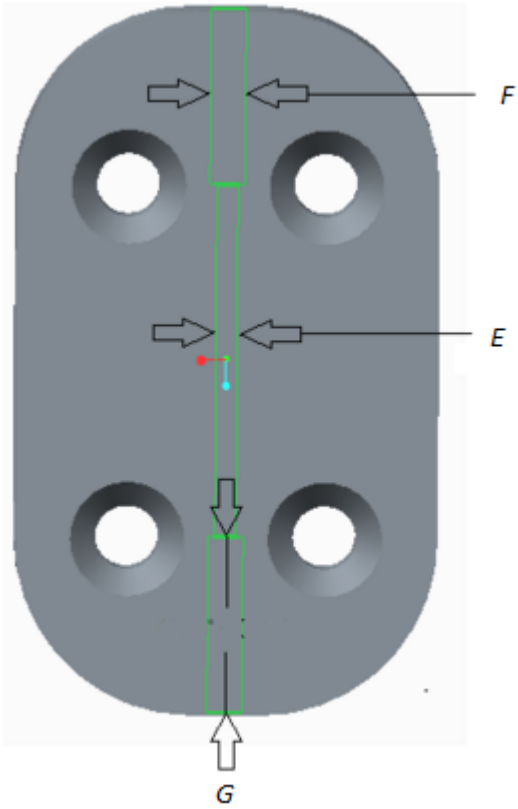
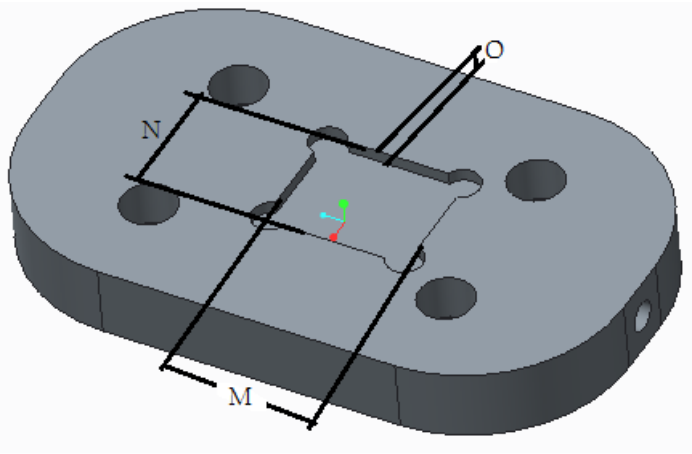


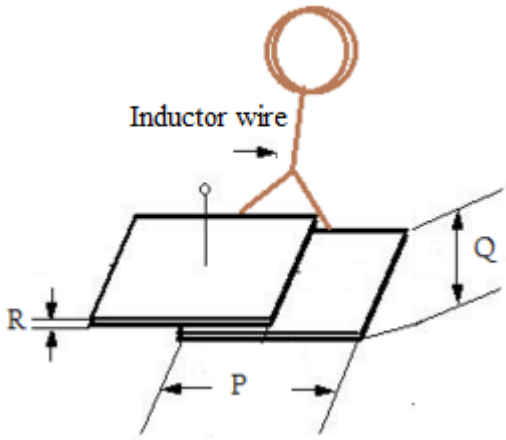
Figure 9: *Channel dimensions within the housing unit*

REQ070: Connections: The pressure and flow sensor packages shall be connected by 0.0394" ± 0.005" tubing that fits over stainless steel tubes extruding from each housing unit (Figure 2) with a pressure of 15 PSI +5 PSI.

Electro-fluidic Interface for Monitoring Brain Injuries

REQ080: Sensors: The package shall have a recession with dimensions 0.24” ± 0.01” x 0.2” ± 0.001” x 0.021” ± 0.005” (M, N, O in Figure 10, respectively) for the placement of a 0.236” ± 0.01” x 0.197” ± 0.001” x 0.0208” ± 0.005” (P, Q, R in Figure 11, respectively) capacitive sensor with an attached inductor wire that coils outside the





housing unit.

Figure 10: *dimensions for the chip groove*

Figure 11: *Chip dimensions and inductor wire. Two chips make up the capacitive sensor, as shown.*

REQ090: Pressure Sensor Distance: The distance from the flow sensor to each pressure sensor (Z, Figure 12) shall be equidistant ± 1% tolerance. The exact distance is 0.5 inches.

BACK090: Change in height between sensors is accounted for in the software coding for pressure values through $-\rho g(h_2-h_1)$.

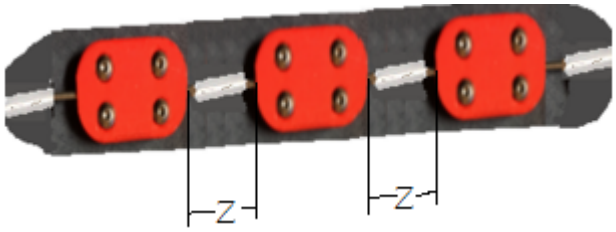


Figure 12: *The distance from the middle housing unit to the outside housing units must be the same*

REQ101: Inductor coil protrusion: The copper wire shall extend from the sensor and protrude through the two halves of the housing unit, as seen in Figure 13.

BACK101A: This is one reason why non-magnetic stainless steel screws are used to compress the package.

BACK101B: The inductor coil is made of copper wire with a thread diameter of 0.5mm, coiled diameter of 25.4mm, and wrapped a total of 2 revolutions.

REQ102: Inductor coil placement: The copper wire shall be placed on the upper part of the housing unit, as seen in Figure 14.

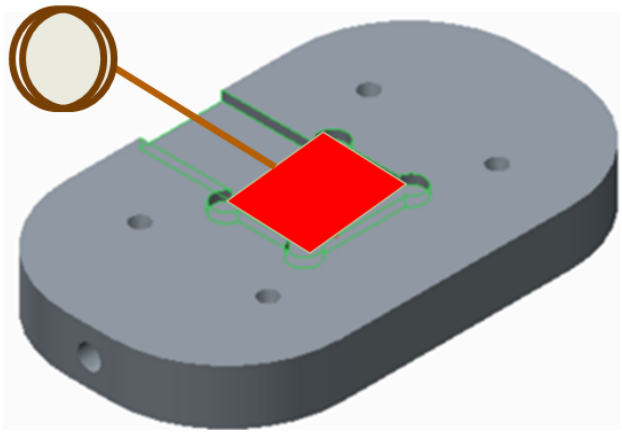


Figure 13: *Visual placement of the sensor, in red, and inductor coil, in gold, on the bottom half of one housing unit.*

Figure 14: *The inductor coil, in gold, originates from the sensor situated between the two halves of a housing unit and loops to rest on the top of the complete housing unit as shown.*

REQ105: Fluid Flow: The channels of the housing unit shall be able to allow flow of cerebrospinal fluid at a maximum rate of 3ml ±1ml per hour.

5.2 Biocompatibility Requirements

This section provides the biocompatibility requirements of the packaging to ensure integration between the product and the internal biological environment.

REQ110: Package: The Packaging Unit shall comply with the biological evaluations (Cytotoxicity, implantation, Biodegradation testing, etc.) as defined by ISO 10993 standards found in document (ISO 10993-3:2014, 10993-6:2007 DOC) and USP Class VI Testing (USP DOC)

BACK110: Poly(methyl methacrylate) or PMMA satisfies the requirements of USP Class VI and ISO 10993 standards (Document: ISO 10993-3:2014, 10993-6:2007 & USP).

REQ120: Screws: Non-magnetic Type 316 Stainless Steel Flat-Head Socket Cap Screws that satisfies degradation requirements of metals in ISO 10993-15:2000, the suitable local effects after implantation in ISO 10993-6:2007, and biocompatibility USP Class VI standards shall be used.

REQ130: Tubing: Medical-Grade Silicone used as the catheter tubing shall satisfy the *in vitro* cytotoxicity standards in ISO 10993-5:2009, the suitable local effects after implantation in ISO 10993-6:2007, and the biocompatibility testing from USP Class VI standards.

REQ140: O-Rings: O-Rings made from EDPM shall satisfy the degradation requirements established in ISO 10993-13:1998 and USP Class VI biocompatibility standards to be suitable for clinical trials.

REQ150: Epoxy: Adhesive epoxy is thermosetting polymer that shall comply with the biological evaluations.

BACK150A: The epoxy can be cured at room temperature -67° F to 500° F.
BACK150B: The epoxy can withstand pressures up to 4000 PSI.

REQ160: Inductor Wires: The inductor coils situated on the top of every housing unit as seen in Figure 7 shall be spray coated with 10ml ± 1ml in medical grade polyurethane and heat cured.

BACK160A: The inductor wire is composed of copper and is extremely susceptible to breakage.
BACK160B: The exposure time to heat during curing is 8 hours.

6. Reliability

This section provides reliability requirements for the biocapacitive sensors, inductors, and receiver module.

REQ310: Sensor Failure Rate: The biocapacitive sensors shall not have more than one failure for the expected 10-year lifetime of the equipment with 95% confidence.

REQ320: **Receiver Failure Rate:** The wireless receiver shall not have more than one failure for the expected 20-year lifetime of the equipment with 95% confidence.